OIPE AUG 13 2008 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

FORSELL

Atty. Ref.: **2333-122**

Serial No. **10/623,801**

Group: **3734; Conf. 5300**

Filed: **July 22, 2003**

Examiner: **Yabut, Diane B.**

For: **MULTI-MATERIAL CONSTRICTION DEVICE FOR FORMING STOMA OPENING**

* * * * * * * * * * * *

RULE 132 DECLARATION OF DR. PETER FORSELL

I, Peter Forsell, declare and state as follows:

1. I am the named inventor in the above-identified application.

2. I am a specialist in General Surgery and have been a member of the Editorial Board of Obesity Surgery in the U.S.A. Besides my medical education and my experience as a medical doctor, I have over 15 years of experience as an inventor, including the design and development of many inventions that are medical devices.

3. I have reviewed the Office Action mailed in the above-identified application on August 15, 2007. I have also reviewed U.S. Patent Application Publication No. 2002/0091395 of Gabby and U.S. Patent Application Publication No. 2002/0099438 of Furst, the two references combined by the Examiner in his claim rejection under 35 U.S.C. § 103(a). In my opinion, one of ordinary skill in the art would not have combined Gabby and Furst, as argued by the Examiner in his § 103(a) rejection, for

the following reasons.

4. Furst discloses an expandable stent for use within a body passageway. A stent is an expandable metal tubular device that is mounted over an angioplasty balloon and deployed at the site of coronary narrowing. The balloon is inflated to expand the stent to physically open and return patency to the body passageway. After the stent is expanded, the balloon is deflated and removed and the stent is permanently disposed to retain the opened body passageway.

5. The objects of the invention according to Furst are to provide a stent that has improved procedural success rates, has higher viability under fluoroscopy in vivo, retains its longitudinal dimensions from its original pre-expanded configuration to its expanded configuration, minimizes damage to tissue during insertion and expansion of the stent, inhibits or prevents the occurrence of in-stent restenosis, vascular narrowing and/or restenosis long after the stent has been inserted into a body passageway, and is simple and cost effective to manufacture.

6. According to Furst, these objects are attained by among other things providing a coating compound securing a biological agent. Furst defines the term "biological agent" as any substance, drug or otherwise, that is formulated or designed to prevent, inhibit and/or treat one or more biological problems, such as, but not limited to, viral, fungus and/or bacteria infection; vascular disorders; digestive disorders; reproductive disorders; lymphatic disorders; cancer; implant rejection; pain; nausea; swelling; arthritis; bone disease; organ failure; immunity diseases; cholesterol problems; blood diseases; lung diseases and/or disorders; heart

diseases and/or disorders; brain diseases and/or disorders; neuroglial diseases and/or disorders; kidney diseases and/or disorders; ulcers; liver diseases and/or disorders; intestinal diseases and/or disorders; gallbladder diseases and/or disorders; pancreatic diseases and/or disorders; psychological disorders; respiratory disorders; gland disorders; skin diseases; hearing disorders; oral disorders; nasal disorders; eye disorders; fatigue; genetic disorders; burns; scars; trauma; weight disorders; addiction disorders; hair loss; cramps; muscle spasms; tissue repair; and/or the like. As such, the term "biological agent" includes vascular active agents and secondary vascular active agents (My underlining). In one embodiment, the "biological agent" includes the "vascular active agents" and "secondary vascular active agents" discussed above.

7. It is thus clear that all problems solved by Furst are directed to vascular matters and biological problems.

8. The present invention relates to a constriction device for forming a restricted stoma opening in the stomach or esophagus of a patient. No such application is disclosed in Furst. On the contrary, a main objective of Furst is to keep the blood passageway open. This objective is attained by providing a biological agent inhibiting and/or reducing restenosis, vascular narrowing and/or in-stent restenosis, see paragraph 0030. The present invention has nothing to do with restenosis or vascular narrowing. The present invention is related to restricting an opening; Furst is related to keeping an opening open.

9. Furst discloses a stent provided with a property improving means on a base material. The base material of a stent is conventionally a rather rigid

material, such as gold, platinum, steel etc. The stent is expanded after insertion into the passageway and is never restricted. Thus, the problems experienced with a stent are remote from the problems experienced with a gastric band and that the person skilled in the art would never look at a stent document when working with gastric banding.

10. With all these differences taken together, it will be realized that the person skilled in the art would not use Furst as relevant prior art when assessing the patentability of the present invention. Even if Furst would be considered to be relevant, the biological agent is not comparable to the property improving means of the present invention.

11. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such wilful false statements may jeopardize the validity of the application or any patents issuing thereon.

Aug 12 2008 — Date

Dr. Peter Forsell